



GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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December 4, 2000

BY HAND DELIVERY

Mr. Joseph A. Levitt
Director
Center for Food Safety and Applied Nutrition
US Food and Drug Administration
200 C Street SW
Washington, DC 20204

Re: Allergens in the Food Supply

Dear Mr. Levitt:

The Grocery Manufacturers of America (GMA) is submitting this letter to inform the agency of the actions that its member companies have taken, and will be taking, to address the presence of allergens in the food supply. We also will be addressing in this letter the issues raised by the State Attorneys General in their May 2000 citizen petition that asked FDA to promulgate new regulations on the labeling of the "Big 8 allergens" (i.e. milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, or soybeans).

The food industry believes that an accurate and reliable label is the best way to address the needs of the food allergic consumer. Such consumers need to know when an allergenic protein derived from a Big 8 allergen is or may be in a product and they need to have confidence that the label is providing this information. With this in mind, many food companies have taken extensive steps over the past several years to address the issues of allergens in the food supply.

The industry recognizes that there is room for continued improvement and is prepared to take additional steps to address the issues of the food allergic consumer. Specifically, GMA is spearheading the development of a Voluntary Allergy Labeling Program (VALP) that would establish guidelines for

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manufacturing and labeling foods that contain allergenic proteins derived from the Big 8 allergens. Once drafted, GMA intends to share the VALP with the Food and Drug Administration (FDA). The industry will be seeking FDA's concurrence with the manufacturing and labeling provisions in the program. GMA believes that such a collaborative agency and industry effort would be the most efficient way to address the needs of the food allergic community. A more thorough discussion follows.

A. The Food Industry Continues to Proactively Address the Allergen Issue

Many in the food industry have been taking numerous measures in the past several years to minimize cross contact with allergenic proteins and to inform consumers about the presence of allergenic proteins derived from the Big 8 allergens. The allergen issue has presented unique challenges to the industry as it strives to provide consumers with a wide variety of products, many of which contain allergenic proteins derived from the Big 8 allergens. The use of shared equipment and other factors can, in rare instances, lead to cross contact with an allergenic protein that is not intended to be in a product formulation.

Many food manufacturers have taken numerous steps to minimize the cross contact with allergenic proteins including those steps listed below.

- Many manufacturers have training programs that educate employees of the importance of preventing cross contact with allergens. By understanding the severity of the reaction that could occur if a food allergic consumer is exposed to an allergenic protein, the employee will be more diligent in his or her efforts to prevent cross contact.
- Many companies have invested in capital improvements, such as adding shields to conveyor belts or redesigning the process by minimizing line crossovers to prevent product in one line from ending up in another line.
- Many food companies have implemented changes in their manufacturing schedules and established procedures for the use of

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rework to reduce the rare occurrences of cross contact with allergens.

- When possible, many manufacturers will add the allergenic ingredients as late in the process as possible to decrease the length of the processing line that will be exposed to the allergen.
- The food industry has actively funded research initiatives such as through its support of groups like the Food Allergy Research and Resource Program (FARRP) at the University of Nebraska-Lincoln.
- Many food companies use "may contain" and other precautionary labeling statements to identify the possible presence of allergenic proteins derived from the Big 8 allergens when cross contact with the allergenic protein cannot be avoided, even when complying with good manufacturing practices.

The industry understands the food allergic consumer's frustration with identifying products that may contain an allergenic protein. The Big 8 allergens are components of many different ingredients, each of which must be identified under the FDA regulations by a separate common or usual name. It is understandably a daunting task to learn the name of every ingredient that could contain the offending allergenic protein. Because of these and other concerns, the GMA member companies are developing the VALP that would take additional steps toward addressing the needs of the food allergic consumer.

B. The Food Industry is Developing a Voluntary Allergen Labeling Program (VALP) that Would Address Allergen Issues

Several industry trade associations currently are developing voluntary guidelines to address the allergen issue. GMA is spearheading the development of the VALP for adoption by its member companies. Although the precise details are still under development, the GMA members have agreed that the program should include the following basic principles.

1. In addition to identifying ingredients by their common or usual name, the food label will contain the easily recognizable name of

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the Big 8 allergen (such as "egg," "milk," or "peanut") from which the ingredient is derived. The VALP would provide various options for presenting this information to the consumer.

2. The name of the Big 8 allergen would appear on the label of products that contain colors or flavors with allergenic proteins derived from the Big 8 allergens.
3. The VALP would recognize that ingredients with allergenic proteins derived from the Big 8 allergens cannot qualify as incidental additives.
4. The VALP would contain guidelines for the use of precautionary statements such as "May Contain ____".
5. The VALP would recognize that the GMP regulations require food manufacturers to take precautionary measures to prevent cross contact with allergenic proteins derived from the Big 8 allergens.

GMA will share this program with other food trade associations and ask their members to support the program. GMA believes that it will be able to develop widespread industry support for the VALP. GMA also will seek comment from the Food Allergy Network (FAN) to make certain that the VALP meets the needs of the food allergic consumer. When completed, the food industry will submit the VALP to the agency for its review and comment.

C. Industry Comments on the Attorneys General Citizen Petition

GMA and its member companies have carefully reviewed the citizen petition filed by the State Attorneys General and we offer the following comments on the provisions in that petition.

1. Use of an "Allergy Information" Statement

The citizen petition would require foods that contain allergenic proteins derived from the Big 8 allergens to bear a warning statement such as: "ALLERGEN INFORMATION: contains wheat and soy." The food industry

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supports the use of easily recognizable names (such as "milk," "wheat" or "peanut") to identify the presence of an allergenic protein in the product. Indeed, the use of easily recognizable names would be the cornerstone of the VALP.

For an allergy program to be successful, however, GMA believes that it must establish accuracy and reliability in the label information while providing manufacturers with sufficient flexibility in determining how best to present the allergy information to the consumer. The VALP would accomplish this first objective by establishing procedures that ensure accurate and reliable information about the presence of an allergenic protein from a Big 8 allergen. The VALP would accomplish this second objective by providing companies with sufficient flexibility in deciding how best to present the allergen information for their products. This flexibility is particularly important for smaller packages where there may be insufficient space for the "Allergy Information Statement" contemplated in the citizen petition.

2. Circle A Symbol

The Attorneys General have asked that the regulations require the use of a "circle A" on the principal display panel of all foods that contain one of the Big 8 allergens. Given the large number of prepared foods that contain one of the Big 8 allergens, this symbol would be rendered essentially meaningless because of the frequency of its appearance. Indeed, in comments posted on their website, the Food Allergy Network (FAN) states that it does not support the use of the circle A symbol because it would appear on so many processed foods. In essence, the circle A would have nominal value because it would not identify the allergenic protein and the food allergic consumer would still need to read the ingredient statement. Because of these and other concerns, the food industry does not support the use of this labeling symbol.

3. Use of a Toll-Free Number on Packages

The citizen petition would require food manufacturers to provide a toll-free number on labels that would enable the food allergic consumer to speak with a trained and knowledgeable customer service representative about the ingredients contained in the food. Many food companies currently provide toll-free numbers on the labels for this and other reasons. A toll-free number, however, cannot serve as a substitute for reading the label. Nor will a toll free number serve as a substitute for

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an accurate and reliable label, which, as state previously, is one of the primary objectives of the VALP.

4. Flavor Designation

The citizen petition would require the labeling of flavors that are derived from the Big 8 allergens. The food industry supports the labeling of flavors or any component with an allergenic protein derived from a Big 8 allergen. Many members of the food industry are providing this information voluntarily. The VALP would require the name of the Big 8 allergen to appear on the label of products that contain any ingredient with an allergenic protein derived from a Big 8 allergens.

5. Incidental Additives

The citizen petition would amend the incidental additive regulations by clarifying that no food ingredient derived from a Big 8 allergen is eligible for classification as an incidental additive. There is no need to pursue rulemaking because the existing FDA policy on incidental additives is protecting the food allergic consumer. The food industry supports the FDA interpretation, as articulated in the June 1996 notice to the food industry, that ingredients that contain allergenic proteins are not incidental additives. The food industry is following this guidance and will be incorporating this policy in the VALP.

The GMA member companies also are concerned about the overly broad nature of the language proposed in the citizen petition. This proposed revision would include all food ingredients derived from the Big 8 allergens, including those that do not contain any allergenic proteins that could induce an allergic reaction. It is well recognized in the scientific community that a specific protein in a food triggers the adverse reaction. It is also recognized that when an ingredient derived from an allergen does not contain the allergenic protein, it will not induce an allergic reaction. By way of example, highly processed and refined oils such as soy oil and peanut oil do not contain allergenic proteins that could trigger an adverse reaction. Because such oils cannot induce an adverse reaction, they should be eligible for classification as an incidental additive when they are present at insignificant levels and have no technical or functional effect in the finished food. ✓

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6. Good Manufacturing Practices

The citizen petition seeks significant changes to the existing Good Manufacturing Practices (GMP) regulation, including the use of dedicated facilities and lines as a means to prevent cross-contact with allergenic proteins. GMA does not believe that this rulemaking is necessary because the existing GMP regulations arguably are sufficiently broad to protect against cross contact with allergens. Indeed, the regulations require manufacturers to take all "*reasonable precautions*" to ensure that production procedures do not contribute contamination from any source. / This and other provisions in the GMP regulations require manufacturers to take reasonable steps throughout the manufacturing operation to prevent inadvertent exposure to allergenic proteins.

Manufacturers have taken steps to identify potential sources of cross contact and have implemented reasonable procedures to minimize the likelihood for cross contact. For example, the manufacturer may use color coded bins to identify raw materials that contain allergenic proteins as a means to alert the employees of the need to handle the ingredient with care to prevent cross-contact. In instances when products are manufactured on shared equipment, manufacturers regularly schedule the production runs to minimize the likelihood for cross contact. When cross contact cannot be prevented by taking these and other reasonable precautions, the industry is using precautionary labeling that informs the consumer that an allergen may be present in the food.

FDA has the tools under its existing GMP regulations and its June 1996 FDA policy on allergens to take enforcement actions against companies that fail to adopt reasonable measures to reduce cross-contact with allergens. In light of this existing regulatory authority, the industry does not believe that additional rulemaking is needed.

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In conclusion, GMA believes that the issues presented by food allergens can best be addressed through a collaborative effort between industry and

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FDA. By working with FDA, industry believes that it can develop and implement a voluntary program that will meet the needs of the food allergic community. Such a collaborative effort will be a more efficient utilization of agency resources than rulemaking and would provide the fastest possible means to address the needs of the food allergic community.

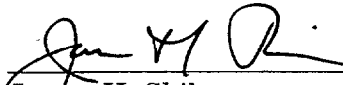
Although the VALP would be voluntary, there are many incentives that increase the likelihood that the program will be followed. Perhaps most important is that the VALP would respond to the needs of the food allergic consumer. Adherence to the VALP would provide the food allergic consumer with important information about the allergenic proteins derived from the Big 8 allergens that are, or may be, in the product.

The industry is developing the VALP and we hope to have a copy available for the Agency's review within the near future. If you have any questions, please do not hesitate to contact us.

Sincerely,



Lisa D. Katic, RD
Director, Scientific & Nutrition Policy



James H. Skiles
Vice President and General Counsel

cc: Kenneth J. Falci, Ph.D., FDA
Martin J. Hahn, Hogan & Hartson L.L.P.